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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

FILED
CLERK'S OFFICE
JUL 14 2004
DISTRICT OF MASSACHUSETTS

BECTON, DICKINSON and COMPANY,)

Plaintiff,)

v.)

THERASENSE, Inc.,)

Defendant.)

Civil Action No. 04-10574 (JLT)

**BECTON DICKINSON'S OPPOSITION TO
THERASENSE'S MOTION TO DISMISS, STAY OR TRANSFER**

Becton, Dickinson and Company ("BD") did not prematurely file this declaratory judgment action during "ongoing" licensing negotiations concerning the patents-in-suit. To the contrary, BD filed suit against TheraSense, Inc. ("TheraSense") only after TheraSense – under new ownership and new management – abandoned its previous negotiating position and insisted upon license terms to which BD could not possibly agree, thereby bringing the negotiations to an impasse.

TheraSense's repeated allegations of infringement throughout the negotiation period gave BD a reasonable apprehension of suit when those negotiations broke down. Under such circumstances, BD was not required (as TheraSense seems to suggest) to wait for TheraSense to file suit against it. Indeed, TheraSense's own patent infringement action against BD, filed in California shortly after BD filed the instant action, makes clear that BD's apprehension of suit was reasonable. The Court should therefore adhere to the standard first-to-file rule and retain jurisdiction over the present case.

I. FACTUAL BACKGROUND

A. The Parties

BD, a medical technology company headquartered in Franklin Lakes, New Jersey, sells a broad range of medical supplies, devices, laboratory equipment, and diagnostic products, including numerous diabetes management products. Declaration of William Marshall in Support of BD's Opposition to TheraSense's Motion to Dismiss, Stay, or Transfer ("Marshall Decl.") at ¶ 2. In addition to manufacturing its own products, BD sells products it has licensed from smaller companies. Id. at ¶ 3.

Nova Biomedical Corporation ("Nova") is a Massachusetts corporation with a principal place of business in Waltham, Massachusetts. Id. Nova is a leading producer of medical biosensors, and manufactures a variety of test strips and monitors for blood glucose level self-testing by diabetics. Id. Specifically, Nova manufactures the BD Logic™ Blood Glucose Monitor ("Logic") product at issue in this case, as well as the test strips used by the Logic system, at its manufacturing facilities in Bedford, Massachusetts. Id. The Logic product can be used by diabetics to self-test blood glucose levels. Id. BD buys the finished Logic product from Nova and re-sells it as part of its medical device portfolio. Id. Nova manufactured the BD Latitude™ Diabetes Management System ("Latitude") product at issue in this case until BD discontinued it in June of 2004. Id.

TheraSense, headquartered in Alameda, California develops, manufactures, and markets blood glucose self-monitoring systems. TheraSense Br. at 2. TheraSense is the assignee of United States Patent Nos. 6,143,164 ("the '164 patent"), entitled "Small Volume In Vitro Analyte Sensor," and 6,592,745 ("the '745 patent"), entitled "Method of Using a Small Volume In Vitro Analyte Sensor with Diffusible or Non-leachable Redox Mediator."

B. TheraSense's Direct Accusations of Infringement

On April 8, 2003, TheraSense's Vice President of Intellectual Property, Patrick Bengtsson, sent a letter to Edward Ludwig, Chairman and CEO of BD, alleging that BD's Logic and Latitude products infringed one or more claims of the '164 patent. Declaration of Wayne M. Kennard ("Kennard Decl."), at Ex. A. In response, by a letter dated April 16, 2003, BD (i) agreed to discuss the matter further; (ii) requested time to review the patent and associated materials; and (iii) asked that TheraSense identify the particular patent claims at issue. Id. at Ex. B. On April 23, 2004, TheraSense identified four claims of the '164 patent as being particularly pertinent. Id. at Ex. C. Subsequently, on July 15, 2003, TheraSense informed BD that the United States Patent & Trademark Office ("PTO") had issued U.S Patent No. 6,592,745 ("the '745 patent"), and that BD's Latitude and Logic products employed methods covered by the '745 patent. Id. at Ex. E.

C. Licensing Negotiations

BD responded to TheraSense's allegations by requesting information about the terms of a possible license for TheraSense's technology.¹ Id.

On July 31, 2003, TheraSense provided BD with the terms of a license proposal. The proposal contained two potential [Redacted] licenses: [Redacted] Id. at Ex. F. From August to October, the parties discussed TheraSense's accusations as well as potential [Redacted] license options. See, e.g., id. at Exs. G-I. On October 31, 2003, Mr. Bengtsson

¹ The parties' communications regarding potential licenses are subject to Fed. R. Evid. 408. BD has referred to these licensing discussions only for the limited purpose of opposing the instant Motion. BD has repeatedly challenged, and continues to challenge, TheraSense's allegations of infringement.

[Redacted]

informed BD's outside counsel, Wayne Kennard, that TheraSense would withdraw its [Redacted] offers on November 20, 2003. Id. at Ex. J.

During this period, Mr. Kennard attempted to set up a face-to-face meeting between the parties. Id. at ¶ 13. On November 19, 2003, Mr. Kennard called Mr. Bengtsson and indicated that BD wanted to bring the parties together for a full discussion of any and all licensing proposals, [Redacted] (notwithstanding the former November 20, 2004 deadline), as well as an alternative [Redacted] licensing arrangement under which [Redacted]. Id. The parties therefore agreed to meet on December 19, 2004. Id.

The parties met at TheraSense's offices on December 19, 2003, and discussed potential licensing terms. Id. at ¶ 16. At the end of that meeting, Mr. Marshall indicated that if a [Redacted] deal did not work, BD would still be interested in pursuing [Redacted] along the lines of the previously-discussed [Redacted] options. Marshall Decl. at ¶ 4. Mr. Lortz acknowledged the comment and said nothing to the contrary. Id.

On December 23, 2003, TheraSense prepared a draft memorandum of understanding setting forth the terms of a [Redacted] licensing agreement and forwarded it to BD for review. Kennard Decl. at Ex. M. Mr. Marshall responded by email on December 29, 2003, noting that: "Another key point I need to ask you to consider is BD's ability to convert to [Redacted]" Id. at Ex. N.

On February 3, 2004, BD told TheraSense that it did not want a [Redacted] license under the terms TheraSense had drafted, but would accept the [Redacted] licensing agreement previously offered by Mr. Bengtsson. Id. at Ex. O. In a follow-up phone call on February 5, 2004, TheraSense's new intellectual property counsel, Douglas Limbach, estimated

that a draft agreement, [Redacted] would be ready in about two weeks. Id. at Ex. P. On February 18, 2004, BD asked TheraSense by email for an approximation of the additional time needed by TheraSense to complete the draft. Id. TheraSense responded that a draft agreement would be completed “mid to late next week.” Id. However, on February 25, Mr. Limbach notified BD that senior management at TheraSense would not be available to review the draft agreement for an additional week. Id.

D. Breakdown in Negotiations

On March 4, 2004, still awaiting a draft agreement from TheraSense, BD contacted TheraSense to inquire if preparation of the draft could be speeded up so that the agreement could be finalized. Id. Mr. Limbach responded that, despite having assured BD on February 5, February 18, and February 25, 2004 that a draft agreement was coming, TheraSense now believed that “it no longer makes sense to complete the draft agreement just yet.” Id. TheraSense advised BD that the primary responsibility for the parties’ licensing discussions was turning over to the new VP of Intellectual Property, Carl Silverman. Id.³

Upon taking control of the process in early March of 2004, Mr. Silverman notified Mr. Marshall on March 10, 2004 that the terms of the offer referenced in BD’s February 3, 2004 acceptance letter : [Redacted] were “unacceptable,” and attached a new term sheet. Id. at Ex. Q. Critically, the new term sheet required that BD undertake to [Redacted]

– requirements BD could not possibly fulfill. Id. Specifically, TheraSense insisted that [Redacted]

Kennard Decl. at Ex. Q at ¶ 5. The term sheet also made several references to “Abbott Laboratories” as a party to the license.

³ In January 2004, Abbott Laboratories (“Abbott”) announced that it had agreed to acquire TheraSense. The acquisition was completed in April 2004. However, based on, among other things, the many references to “Abbott” in TheraSense’s March 10, 2004 letter to BD, it appears that Abbott was already controlling negotiations.

TheraSense's March 10, 2004 letter represented a complete break from the parties' previous discussions. Marshall Decl. at ¶ 5.

On March 18, 2004, Mr. Kennard replied, stating that the March 10, 2004 terms were inconsistent with previous negotiations and renewing BD's request for the reinstatement of [Redacted] Kennard Decl. at Ex. R. Specifically, Mr. Kennard requested that TheraSense acknowledge its agreement to [Redacted] by close of business on March 22, 2004. Id. at Ex. R at 2. TheraSense did not sign the acknowledgment by March 22, 2004. Id. at ¶ 23.

On March 23, 2004, Mr. Kennard called Mr. Silverman to ascertain TheraSense's response to his most recent letter. Id. When Mr. Silverman indicated that TheraSense was no longer willing to offer a license [Redacted] and was instead insisting on [Redacted]

, Mr. Kennard indicated that he would have to protect his client's interests. Id. Mr. Silverman responded that "Well, you've got to do what you've got to do." Id. Mr. Kennard understood from this conversation that, given TheraSense's refusal even to consider [Redacted] and its insistence on the Nova terms, litigation between the parties was inevitable. Id.

Facing a renewed threat of litigation, and impossible licensing demands, BD filed the present lawsuit on March 23, 2004. Id. at ¶ 24. Shortly thereafter, TheraSense filed suit against BD in the Northern District of California on the very same patents.

II. ARGUMENT

BD did not file suit until it had become clear that TheraSense – under new ownership and new management – had abandoned its earlier negotiating position and was insisting on terms to which BD could not possibly agree. Abbott Laboratories' purchase of TheraSense, and Mr. Silverman's concomitant assumption of all licensing decisions, marked the end of negotiations and the resumption of a threat of suit. Between March 10, 2004 and March 23, 2004, BD took steps to revive the negotiations. When those efforts failed, litigation became likely if not

inevitable. TheraSense's subsequent California suit further confirms that BD's earlier apprehension of suit was reasonable.

The Court should therefore apply the standard first-to-file rule and order that the case proceed here.

I. The Court Has Jurisdiction Over This Action Because BD Had A Reasonable Apprehension Of Suit When It Filed.

The Declaratory Judgment Act, 28 U.S.C. § 2201(a), grants United States courts jurisdiction over declaratory judgment actions in cases of "actual controversy." The Federal Circuit has found that an actual controversy exists when two criteria are met: "(1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." Fina Research v. Baroid Limited, 141 F.3d 1479, 1481 (Fed. Cir. 1998); Arrowhead Industrial Water, Inc. v. Ecochem, Inc., 846 F.2d 731, 736 (Fed. Cir. 1988).

In the instant action, BD's sale of the Logic and Latitude products easily satisfies the second prong of the test. At issue, therefore, is whether the first prong of the test – "reasonable apprehension" of an infringement suit – was satisfied as of March 23, 2004, the date BD filed its complaint. In the absence of an overt threat, the "totality of the circumstances" must be considered in evaluating whether a reasonable apprehension of infringement litigation exists. Cargill v. Scars Petroleum, No. 02-1396, 2002 U.S. Dist. LEXIS 20714 at *8 (S.D.N.Y. 2002).

TheraSense had already made clear its willingness to sue. In its April 8, 2003 letter, TheraSense stated, "We take the issue of patent infringement seriously." Id. at Ex. A. In its July 31, 2003 letter, TheraSense stated, "The continued sale of BD's unlicensed infringing product is of great concern to TheraSense." Id. at Ex. F. In its August 8, 2003 letter, TheraSense stated,

“Each week of further infringement by BD results in greater damage to TheraSense . . .”. Id. at Ex. J. And during their November 19, 2003 conversation, Mr. Bengtsson indicated to Mr. Kennard that TheraSense was prepared to “do whatever was necessary to protect its rights” if the parties failed to enter a license. Id. at ¶ 13. Such repeated accusations and inferences gave BD a reasonable apprehension of suit. See Tactical Software, LLC v. Digi International, Inc., 2003 U.S. Lexis 18831 (D.N.H. 2003) (finding a reasonable apprehension of suit from patentee’s continued assertions of infringement during licensing negotiations, and noting that “the presence of ongoing negotiations does not necessarily preclude the conclusion that there is a case or controversy”). A patentee does not need to expressly state his intent to sue in order to raise a reasonable apprehension. Arrowhead, 846 F.2d at 736 (“If defendant has expressly charged a current activity of the plaintiff as an infringement, there is clearly an actual controversy, certainty has rendered apprehension irrelevant, and one need say no more.”); Blistex Inc. v. Circle Laboratories, Inc., 2000 WL 1154635, *1 (N.D.Ill. 2000).

Any comfort the negotiations may have provided to BD disappeared on March 10, 2004, when TheraSense announced that its own earlier proposal (i.e. [Redacted]) was now “unacceptable”, and proffered unreasonable terms to which BD could not agree. See Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha, 57 F.3d 1051, 1053 (Fed. Cir. 1995) (“[w]hen there are proposed or ongoing license negotiations, a litigation controversy normally does not arise *until the negotiations have broken down.*”) (emphasis added); Cf. Findwhat.com v. Overture Services, Inc., 2003 U.S. Dist. Lexis 2450, *4 (S.D.N.Y. 2003) (finding a reasonable apprehension of suit despite ongoing licensing negotiations). Abbott Laboratories had taken control of TheraSense, replaced Douglas Limbach with Carl Silverman, and radically changed its negotiating position. [Redacted] TheraSense’s

implied threat of suit – if ever dormant – was revived. When Mr. Kennard closed his conversation with Mr. Silverman on March 23, 2004, Mr. Silverman essentially admitted that litigation was likely, if not inevitable, saying: “Well, you’ve got to do what you’ve got to do.” Id. at ¶ 23. TheraSense filed its own suit against BD shortly thereafter.

In sum, the totality of circumstances demonstrates that BD had a reasonable apprehension of litigation when it filed the present declaratory judgment action, and that there was an “actual controversy” between the parties.

II. The Court Should Not Decline to Exercise Jurisdiction.

Contrary to TheraSense’s assertions, BD has not engaged in an “improper attempt . . . to preempt TheraSense’s chosen choice of forum,” TheraSense Br. at 8, or any inequitable conduct that would justify declining jurisdiction. To the contrary, BD simply exercised its right to file a declaratory judgment action in the wake of TheraSense’s infringement accusations. Genentech, Inc. v. Eli Lilly & Co., 998 F.2d 931, 937 (Fed. Cir. 1993) (“the purpose of the Declaratory Judgment Act is to enable a person to caught in controversy to obtain resolution of the dispute instead of being forced to await the initiative of the antagonist”), abrogated on other grounds Wilton v. Seven Falls, Co., 515 U.S. 277 (1995).

Courts have long recognized a strong presumption in favor of the first-filed action. See Genentech, 998 F.2d at 938 (the first-to-file rule should be followed absent “sound reason that would make it unjust or inefficient to continue the first-filed action.”). Lower courts in this district and elsewhere have followed the holding of Genentech. See, e.g., Biogen, Inc. v. Schering AG, 954 F. Supp. 391, 399 (D. Mass. 1996) (refusing to dismiss first-filed declaratory judgment action in favor of second-filed infringement suit); Holmes Group, Inc. v. Hamilton Beach/Proctor Silex, Inc., 249 F. Supp. 2d 12, 19 (D. Mass. 2000) (refusing to transfer first-filed

declaratory judgment action to district where second-filed patent infringement case has been filed). See also Abbott Laboratories, Inc. v. Mead Johnson & Co., Case No. C2-98-0157, 1998 U.S. Dist. LEXIS 12317 at *16-17 (S.D. Ohio 1998) (transferring later-filed patent infringement suit to district where first-filed declaratory judgment action was pending and noting that court could not “consistent with notions of comity and conservation of judicial resources, commandeer the authority of the first first-filed court’s role”); Guthy-Renker Fitness, LLC v. Icon Health & Fitness, 179 F.R.D. 264, 274 (C.D. Cal. 1998) (refusing to transfer first-filed declaratory judgment action to district where second-filed patent infringement case had been filed).

Any departure from the first-to-file rule rests with the sound discretion of the Court. Genentech, 998 F.2d at 938-9. “No single presumption or factor will always control, and instead, the result will depend on factual nuances.” Reebok Intl. Ltd. v. Dunkadelic Inc., 2004 WL 413266 (D. Mass. 2004) (retaining jurisdiction over a first-filed declaratory judgment action where the plaintiff had not raced to the courthouse the day the defendants threatened litigation.).

Here, BD’s conduct was fair and reasonable and does not warrant a departure from the first-to-file rule. In a series of phone calls and emails in February 2004, TheraSense apparently had accepted BD’s February 3, 2004 proposal. See Kennard Decl. at Ex. P. On February 5, 2004, TheraSense’s in-house patent counsel, Douglas Limbach, indicated that TheraSense would produce a draft based on the February 3rd letter in approximately two weeks. Id. On February 18, 2004, he indicated that TheraSense was still working on a draft, but needed another week. Id. On February 25, 2004, he again apologized for TheraSense’s delay, indicated that TheraSense’s management was still actively considering BD’s proposal. Id. Only on March 4, 2004, did Mr. Limbach indicate that Mr. Silverman was taking over and that “it no longer makes sense to complete the draft agreement just yet.” Id.

Carl Silverman – not BD – finally derailed negotiations on March 10, 2004, stating that the proposal was “unacceptable.” Id. at Ex. Q. By inserting the Nova terms, Mr. Silverman made litigation substantially more likely, if not inevitable. The Court should not depart from the first-to-file rule under such circumstances.

Other courts, facing similar facts, have held that ongoing negotiations do not prevent an accused infringer from choosing the forum of its declaratory judgment action. In Russell Corp. v. Sara Lee Corp., 129 F. Supp.2d 1165, 1168 (N.D. Ill. 2001), after finding that the patentee’s aggressive statements gave rise to jurisdiction, the court rejected the patentee’s invitation to decline that jurisdiction on the grounds that the parties were engaged in licensing negotiations. Id. The court retained jurisdiction, noting there was “[no] rule that so long as a license has been proposed, the alleged infringer should be precluded from bringing a declaratory judgment action.” Id. at 1169.

Case law cited by TheraSense is not to the contrary. Neither Davox Corp. v. Digital Systems Int’l, 846 F. Supp. 144 (D. Mass. 1993) nor Philips Plastic involved negotiations. Judge Wolf in Davox declined jurisdiction only because the accused infringer had sent a letter stating it would respond to the patentees accusations, and instead filed suit. See Davox, 846 F.Supp. at 148 (“Rather than responding to the invitation to enter into discussions to resolve the matter, as Davox represented it would, Davox filed this action in an evident effort to obtain a forum more convenient...”). In Philips Plastic, the patentee suggested the accused infringer enter licensing discussions and the accused infringer immediately filed suit. Phillips Plastics, 57 F.3d at 1053. By contrast, BD spent over eight months attempting to negotiate a license with TheraSense (while arguing that no such license was even necessary) and only filed suit after negotiations had broken down.

Kleinerman v. Luxtron Corp., 107 F. Supp.2d 122 (D. Mass. 2000) is similarly distinguishable. In Kleinerman, Judge Gorton noted that the accused infringer had *not* run to the courthouse immediately, but had engaged in eight months of negotiation. Id. at 124. Where Luxtron went wrong, Judge Gorton stated, was in “pouncing” at the first sign of an impasse. In the instant case, BD did not “pounce.” After TheraSense indicated it would not discuss [Redacted], Mr. Kennard nevertheless made an attempt to revive the licensing negotiations in a March 18, 2004 letter. Only after Mr. Silverman made clear he would not retreat from his demands did BD file suit.

III. The Court Should Not Transfer The Case To Another Venue Under 28 U.S.C. § 1404(a).

The Court should also reject TheraSense’s motion to transfer the case pursuant to 28 U.S.C. § 1404(a). As a starting point for the Court’s analysis, TheraSense bears a heavy burden under § 1404(a). “The party seeking to demonstrate that one forum is more convenient than another . . . must show that the plaintiffs choice of forum is substantially more inconvenient than the alternative proposed by it.” Kleinerman, 107 F.Supp.2d at 125.

TheraSense has identified six factors the Court should consider in deciding whether to transfer the case: (1) the plaintiff’s choice of forum; (2) the convenience of the parties; (3) the convenience of witnesses and the location of documents; (4) any connection between the forum and the issues; (5) the law to be applied; and (6) the public interest. See also, e.g., Veryfine Products, Inc. v. Phlo Corp., 124 F.Supp.2d 16, 24 (D. Mass. 2000).

1. The plaintiff’s choice of forum

This factor favors Massachusetts. As noted above, the plaintiff’s choice of forum is owed considerable deference. “Where identical actions are proceeding concurrently in two federal courts, entailing duplicative litigation and a waste of judicial resources, the first-filed action is

generally preferred in a choice-of-venue decision.” Reebok, 2004 WL 413266 at *3 (refusing to transfer a first-filed declaratory judgment action).

TheraSense’s observation that BD is headquartered in New Jersey misses the mark. Courts defer to first-filed actions where the plaintiff has filed suit in its home district, since “such a choice usually represents considerations of convenience rather than harassment of the defendant.” Holmes Group, 249 F.Supp.2d at 17. Nova, headquartered in Massachusetts, designed, developed, and manufactured the Logic and Latitude products distributed by BD at issue in this case. In a patent infringement suit such as this one, both parties will need to analyze Nova’s products and files. As such, the choice of Massachusetts “represents considerations of convenience rather than harassment of the defendant.”

2. The convenience of the parties

BD and TheraSense would experience corresponding (and roughly equal) inconvenience by traveling to each other’s chosen forum.⁴ TheraSense’s counsel is located in California. BD’s counsel is located in Massachusetts. On balance, this factor favors neither forum.

3. The convenience of witnesses and the location of documents

This factor favors Massachusetts. BD’s documents and witnesses are relatively close to Massachusetts. TheraSense’s documents and witnesses are located in California. Nova breaks the tie. Nova’s documents and witnesses concerning product design, development, and manufacture are all located in Massachusetts and will feature prominently in TheraSense’s infringement case. Taken as a whole, Massachusetts will be more convenient for all of the witnesses.

4. Any connection between the forum and the issues

⁴ New Jersey is a very short flight from Boston and the federal courthouse.

As noted above, BD and Nova are both located in Massachusetts. Nova is headquartered in Massachusetts. Since the outcome of this case will dramatically affect Nova's ability to sell a core product, Massachusetts has a strong interest in the case. At the same time, California does have an interest in TheraSense's business dealings. On balance, this factor favors neither forum.

5. The law to be applied

This factor is neutral, since Federal Circuit patent law will govern the case regardless of forum.

6. The public interest.

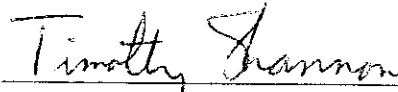
While the public interest will be largely unaffected by the choice of venue in this case, the Court should consider the potential burden on the respective Courts. See, e.g., Colbond, Inc. v. North American Green, Inc., 2000 U.S. Dist. Lexis 21304, *7 (W.D.N.C. 2000) (considering "court congestion" in determining a motion to transfer under sec. 1404(a)). The United States District Court for the District of Massachusetts had 340 pending actions per judgeship in 2003. See Federal Judicial Center, Judicial Caseload Profile Report (www.uscourts.gov/cgi-bin/cmsd2003pl) (attached hereto as Exhibit 1). The United States District Court for the Northern District of California had 541 pending actions per judgeship in 2003. See id. In the interest of equitable caseload distribution, this Court should retain jurisdiction over the pending action.

WHEREFORE, BD respectfully requests that the above-referenced Opposition and Declarations be filed under seal until further hearing.

Respectfully submitted,

BECTON, DICKINSON AND COMPANY

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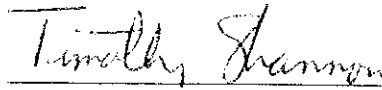
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Date: July 1, 2004

LOCAL RULE 7.1 CERTIFICATION

Counsel for BD has attempted, by telephone, to contact counsel for TheraSense concerning the instant Motion, but has so far been unable to contact such counsel.



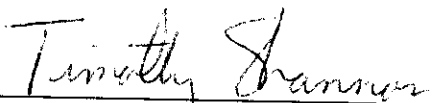
Timothy R. Shannon

CERTIFICATE OF SERVICE

I, Timothy R. Shannon, hereby certify that on July 14, 2004, I caused a copy of this document to be served on counsel of record listed below.

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